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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/998,250 | 11/30/2001 | Shoukat Dedhar | KINE001CIP5 | 5685 |

24353 7590 06/04/2003

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| EXAMINER |
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CRIARES, THEODORE J

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| ART UNIT | PAPER NUMBER |
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1617

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DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,250

Applicant(s)

DEDHAR ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 1-10 and 13 in Paper No. 9 is acknowledged.

Applicants request for rejoinder of Group IV has been noted and will be addressed after allowance of claims in the subject application.

Claims 11, 12 and 14 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10, and 13 are rejected under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

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Nature of the Invention: All of the rejected claims are drawn to a method of treating inflammation in a subject with an effective amount of compounds which are inhibitors of integrin linked kinase (ILK) wherein said inhibitor is a "small organic molecule". The nature of the invention is extremely complex in that it encompasses the actual determination of what is a small organic molecule.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass compounds which are defined at page 5 within U.S. Patent 6,177,273 which teach and disclose from column 6, line 8 to column 10, line 47 a vast number of compounds which meet applicants broad claim.

Guidance of the Specification: The guidance given by the specification would not teach the skilled artisan which patent or which compounds will have the activity claimed by applicants..

Working Examples: The application provides only one example of a compound MC-5 as an anti-inflammatory agent. It is to be noted that the chemical name is not given for this compound.

State of the Art: While the state of the art is relatively high with regard to treatment of inflammation the compounds which treat such a disorder are numerous and would fall within applicants broad claim to a "small organic molecule"...

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual treatment of inflammation using a "small organic molecule" since it fails to identify MC-5.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to envision the small organic molecule selected from the vast number of patents cited within applicants specification and U>S> 6,177,273 in combination of appropriate pharmaceutical carrier, dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for treating inflammation. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art what small organic molecule is the compound claimed, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art to the group of compounds claimed, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treat inflammation in a subject by administration of an "small organic molecule" as claimed by applicants..

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Therefore, a method of treating inflammation ~~preventing~~ in a subject by administering a "small organic molecule" ^{is} not considered to be enabled by the instant specification.


None of the claims are allowed.

Applicants are requested to review their patent portfolio to avoid Double Patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
June 2, 2003

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